USP Analysis of Sorbitol on an Agilent Hi-Plex Pb Column

Application Note

Pharmaceutical

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Introduction

Sorbitol is a sugar alcohol that is metabolized slowly by the body. Also known as glucitol, sorbitol is commercially produced by the reduction of glucose, during which the aldehyde group is changed to an additional hydroxyl group.

Sorbitol is found in stone fruits, such as peaches and plums, as well as in berries. It is often used as a sugar substitute in foods such as ice cream, as well as in sugar-free gum. It is nutritive in that it contains calories, but it is not sticky like dextrose or glucose solutions. It is also used in tobacco products to give texture and maintain moisture as a humectant. Sorbitol is resistant to metabolism by oral bacteria that break down sugars and starches to release acids, which may lead to cavities or erode tooth enamel, and so it is a common ingredient in toothpaste.

Sorbitol is also found in pharmaceutical applications, where it is used as an excipient or as a primary ingredient. As an excipient, it is useful because it can be compressed into tablet forms and its sweetness provides an excellent mask to many drugs. As an active ingredient, it can be used to treat constipation or as an irrigation solution during urinary tract surgery.

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Instrumental

According to the USP method, sorbitol is analyzed using a liquid chromatograph equipped with a refractive index (RI) detector, maintained at 50 °C, and a 7.7 × 100 mm column packed with a strong cation-exchange resin consisting of sulfonated crosslinked styrene/divinylbenzene copolymer in the lead form, classified as L34. The column temperature is maintained at 50 °C, with a flow rate of 0.7 mL/min. The system suitability test (SST) used in this analysis is a mixture of sorbitol and mannitol, which is an isomer of sorbitol.

Conditions

Column	Agilent Hi-Plex Pb USP L34, 7.7 × 100 mm, 8 µm (p/n PL1170-2820)
Mobile phase	100% DI H_2O
Flow rate	0.7 mL/min
Temperature	50 °C
Detector	RI

Sample Preparation

A solution of sorbitol and mannitol, used as an internal standard, is made up to contain 4.8 mg/mL of each compound. The requirement for this assay is that the relative retention times are about 0.6 for mannitol and 1.0 for sorbitol, with a resolution of not less than 2.0 between them.

Peak identification

1. Mannitol
2. Sorbitol

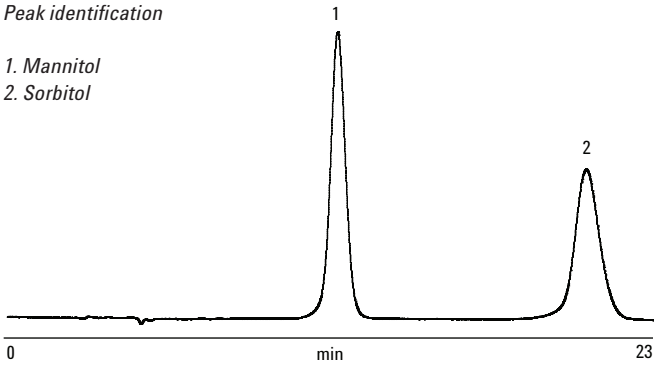

Figure 1. Raw data chromatogram of sorbitol and mannitol on an Agilent Hi-Plex Pb USP L34 column.

For More Information

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